

ICU Medical's New ChemoLock[™] Needlefree Closed System Transfer Device (CSTD) Receives First-Ever FDA 510(k) Clearances for Both Pharmacy and Patient Administration Applications

ChemoLock Protects Patients and Caregivers From Exposure to Hazardous Drugs and is the First and Only All New CSTD to Meet Current Guidance Standards and Receive FDA Classifications for Both Pharmacy Preparation (ONB) and Patient Administration (FPA)

SAN CLEMENTE, Calif., September 9, 2013 – ICU Medical, Inc. (NASDAQ: ICUI) today announced that its ChemoLockTM needlefree closed system transfer device (CSTD) is the first and only CSTD to receive United States Food and Drug Administration (FDA) 510(k) clearance for pharmacy applications (product code ONB), as well as patient administration applications (product code FPA) that adhere to current guidance standards, which were updated in 2008.

"We designed ChemoLock as an intuitive needlefree system to keep pharmacy and nursing staffs and their patients safe from exposure to hazardous drugs," explained ICU Medical CEO Dr. George Lopez. "By preventing the transfer of environmental contaminants into the system



ICU Medical's ChemoLock system keeps clinicians and patients safe from exposure to hazardous drugs.

and blocking the escape of drug or vapor concentrations outside the system, ChemoLock will keep clinicians and patients safe from exposure to a wide range of hazardous drugs—including those used in chemotherapy—while maintaining the sterility of the drugs themselves."

The ChemoLock system consists of easy to use needlefree components that connect with an audible click, cannot be deactivated, and will passively aid in preventing both needlestick injuries and the exposure cytotoxic medications. No complex assembly is required prior to usage and the system remains completely closed throughout the entire safe handling process—including preparation, transportation, administration, and disposal—assuring both patient and caregiver safety as well as the sterility of the prepared medication.

"ChemoLock is a mechanically and microbiologically closed needlefree system that is safe, intuitive, and easy to use during every step of the hazardous drug handling process, helping assure compliance with OSHA, NIOSH, ASHP, ISOPP, ONS, APHON and USP <797> safe-handling guidelines," explained Robert Houde, RPh, Director of ICU Medical's Oncology Division. "It offers significant advantages over competitive products on the market, and is a perfect complement to our current product line, which includes the ChemoClave[®] CSTD and Closed System product line and the Diana[™] hazardous drug compounding system. No other company can offer customers the range of safe handling solutions that we do."

Currently in limited market release and in clinical use at several early adopter hospitals throughout the United States and Europe, ChemoLock will be formally introduced and available later this year, and will be featured at the American Association of Hospital Pharmacists' (ASHP) midyear meeting and exposition in Orlando, FL in December.

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About ICU Medical, Inc.: ICU Medical, Inc. develops, manufactures and sells innovative medical devices used in vascular therapy, oncology and critical care applications. ICU Medical's products improve patient outcomes by helping prevent bloodstream infections and protecting healthcare workers from exposure to infectious diseases or hazardous drugs. The company's complete product line includes custom IV systems, closed delivery systems for hazardous drugs, needlefree IV connectors, catheters and cardiac monitoring systems. ICU Medical is headquartered in San Clemente, California. More information about ICU Medical, Inc. can be found at www.icumed.com.

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